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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,603	10/03/2006	Gerd Bartoszyk	613242000900	5390

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EXAMINER	
BAEK, BONG-SOOK	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,603	BARTOSZYK, GERD	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,20-23 and 34-39* is/are pending in the application.

4a) Of the above claim(s) *23 and 34-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14, 20-22, and 37-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/6/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

The amendment filed on 10/6/2008 is acknowledged. Claims 1-13, 15-19, and 24-33 were previously canceled and claims 23 and 34-36 have been withdrawn. Claims 14 and 37 have been amended and claims 14, 20-22, and 37-39 are under examination in the instant office action.

Applicants' arguments, filed on 10/6/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. Responses are limited to Applicants' arguments relevant to either reiterated or newly applied rejections.

Information Disclosure Statement

Information Disclosure Statements have been filed with a fee on 10/6/2008 after receipt of a first Office Action on the merit but before mailing of a Final Office action or Notice of Allowance. A signed and initialed copy of the IDS paper filed on 10/6/2008 is enclosed in this action.

New ground of rejections necessitated by Applicant's amendment

Applicant' amendment requiring "systemic administration" necessitated the following rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 20-22, and 37-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over US patent 6,060,504 in view of Cunningham *et al*. (BMJ, 321:778-779, September 2000).

US patent 6,060,504 teach N–methyl-N-[(1S)-1-phenyl-2-((3S)-3-hydroxypyrrolidin-1-yl)ethyl]-2,2-diphenylacetamide and its physiologically acceptable salt such as N–methyl-N-[(1S)-1-phenyl-2-((3S)-3-hydroxypyrrolidin-1-yl)ethyl]-2,2-diphenylacetamide hydrochloride (asimadoline) and the use of the compound for severe pain, hypersensitivity to pain, in particular inflammation-related hyperalgesias, and inflammation (column 1, lines 6-12 and lines 53-63, column 2, lines 4-9, example 1). The reference further teaches pharmaceutical preparations of the compound for oral, rectal, and parenteral administration and further discloses that the oral administration (considered as systemic administration) is preferred (column 5, lines 28-34 and lines 59-60).

US patent 6,060,504 differs from the instant claims insofar as it does not specifically teach use of asimadoline for the treatment of post-herpetic neuralgia.

Cunningham *et al*. teach that post-herpetic neuralgia is a complication after herpes zoster and is associated with scarring of the dorsal root ganglion and atrophy of the dorsal horn on the affected side (neuropathy), which follows the extensive inflammation and these and other

abnormalities of the peripheral and central nervous system produce the pain and other unpleasant symptom of post-herpetic neuralgia, which include allodynia and hyperalgesia (p778, left column 2nd paragraph-right column, 1st paragraph). They further suggest that in addition to antiviral treatment, other drugs such as topical lidocaine and oxycodone that have been shown to be efficacious in treating chronic neuropathic pain should be evaluated in patients with herpes zoster (p779, right column, 3rd paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use asimadoline taught by US patent 6,060,504 for the treatment of post-herpetic neuralgia with a reasonable expectation of success because of the following reasons: US patent 6,060,504 teaches that asimadoline is effective for the treatment of severe pain, hyperalgesias, and inflammation, which are typical symptoms of post-herpetic neuralgia as taught by Cunningham *et al*. In addition, Cunningham *et al*. suggest that topical lidocaine and oxycodone, which are commonly used for severe pain, are effective for neuropathic pain and can be used for patients with herpes zoster. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use asimadoline for the treatment of post-herpetic neuralgia since asimadoline, which is effective for severe pain, hyperalgesias, and inflammation, is expected to be useful for treating such symptoms of post-herpetic neuralgia.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities) and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 8:00-5:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
Bbs

BONG-SOOK BAEK
Examiner, Art Unit 1614